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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/781,564

02/18/2004

James P. Quigley

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9290

21186

7590

11/07/2008

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EXAMINER

SANG, HONG

ART UNIT

PAPER NUMBER

1643

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/781,564	<b>Applicant(s)</b> QUIGLEY ET AL.	
	<b>Examiner</b> HONG SANG	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 34-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 34 and 36 is/are allowed.
- 6) ☒ Claim(s) 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Exhibits A-C</u> .                     |

## **DETAILED ACTION**

**RE: Quigley et al**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/31/2008 has been entered.
2. Applicant's supplemental response filed on 10/31/2008 is acknowledged. Claims 1 and 34-36 are pending. Claims 2-33 have been cancelled.
3. Claims 1 and 34-36 are under examination.

### ***Drawings***

4. The replacement drawings were received on 9/11/2008. These drawings are acceptable.

### ***Sequence Listing***

5. The substitute sequence listing (both in paper and computer readable form) and the statement were received on 9/11/08.

***Priority***

6. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/448,828, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for claims 34-36 of this application. Although Application No. 60/448,828 discloses SEQ ID NO: 1 and contemplates the variants of SEQ ID NO: 1. There is no disclosure of the variant of SEQ ID NO: 1, wherein the variant results from the substitution of the glutamine with an arginine at amino acid 525, the substitution of the aspartic acid with a glycine at amino acid 709, or the substitution of the asparagine with a serine at amino acid 827. Accordingly, claims 34-36 are only entitled to the date of the instant application, which is 2/18/2004.

If applicant believes that support for claims 34-36 is present in the earliest filed priority document, applicant must, in responding to this action, point out with particularity, where such support may be found.

***Rejections Withdrawn***

7. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by accession no. BAB15511 (see IDS, first seen at NCBI 9/30/2000) is withdrawn in view of applicant's amendment to SEQ ID NO: 1.

8. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by accession no. Q9H5V8 (See accession no. Q9H5V8 information sheet, and revision history, release date: 3/1/2001) is withdrawn in view of applicant's amendment to SEQ ID NO: 1.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Schweifer et al. (WO 02/04508A1, Pub. Date: 1/17/2002, IDS, English equivalent US 2002/0142003A1, Pub. Date: 10/3/2002).

Schweifer et al. teach a tumor-associated protein B345 consisting of SEQ ID NO: 4 (see claim 1). Schweifer et al. teach recombinant expression of B345 protein in human cell line (see paragraph [0035]). The recombinant B345 protein produced in human cell line would be glycosylated. The amino acid sequence of SEQ ID NO: 4 is 100% identical to the variant of SEQ ID NO: 1, wherein the variant results from the substitution of the aspartic acid with a glycine at amino acid 709 (see Exhibits A and C).

11. Claims 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Tang et al. (WO 02/070539A2, Pub. Date: 9/12/2002).

Tang et al. teach an isolated polypeptide comprising SEQ ID NO: 1600 (see claim 9). Tang et al. teach recombinant production of the polypeptide using mammalian cell culture system (see page 27). The recombinant protein made in mammalian cell culture system would be glycosylated. The amino acid sequence of SEQ ID NO: 1600 is 100% identical to the variant of SEQ ID NO: 1, wherein the variant results from the substitution of the aspartic acid with a glycine at amino acid 709 (see Exhibit B).

It is noted that due to the large volume of the cited WO document (total pages 1012), only the relevant pages (pages 1, 27 and 1008) are enclosed in the office action.

### ***Conclusion***

12. Claims 1, 34 and 36 are allowable. Claim 35 is rejected.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/  
Examiner, Art Unit 1643  
11/5/08